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PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XCI. Wholesale Drug Distributors

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Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XCI. Wholesale Drug Distributors

Chapter 1. General Provisions

§101. Authority

A. These rules of practice and procedure are promulgated in accordance with the Louisiana Administrative Procedure Act. All Rule making and hearing procedures of this board are conducted according to the Louisiana Administrative Procedure Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:381 (April 1992).

§103. Definitions

A. As used in this regulation, unless the context otherwise requires.

Blood—whole blood collected from a single donor and processed either for transfusion or further manufacturing.

Blood Component—that part of blood separated by physical or mechanical means.

Board—the Louisiana Board of Wholesale Drug Distributors.

Controlled Substance—those substances, drugs, or immediate precursors listed in Schedules I through VI of the Uniform Controlled Substances Act.

Drug Sample—a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

Legend Drug

a. a drug limited by Section 503(b)(1) of the federal Food, Drug, and Cosmetic Act to being dispensed by or upon a licensed practitioner's prescription because the drug is:

- i. habit-forming;
- ii. toxic or having potential for harm;
- iii. limited in its use to use under a practitioner's supervision by the new drug application for the drug.

b. The product label of a legend drug is required to contain the statement "Rx Only" or "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION."

c. A legend drug includes prescription drugs subject to the requirement of Section 503(b)(1) of the federal Food, Drug, and Cosmetic Act, which shall be exempt from Section 502(F)(1) if certain specified conditions are met.

Manufacturer—anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

Person—individual, partnership, corporation, business firm and association.

Prescription Drug—any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act.

Wholesale Distribution and Wholesale Distributions—the distribution of prescription drugs to persons other than consumers or patients, but does not include:

a. sale or transfer between any division, subsidiary, parent and/or affiliated or related company under common ownership and control, or a sale to a customer to cover a particular unforeseen need or from such a common ownership facility as certified by a licensed facility;

b. the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization from the group purchasing organization or from other hospitals or health care entities that are members of such organization;

c. the sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the federal Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

d. the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under *common control*; for the purposes of this regulation *common control* means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock, voting rights, by contract or otherwise;

e. the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this regulation, *emergency medical reasons* include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage that arises from delays in or interruptions of regular distribution schedules;

f. the sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription;

g. the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

h. the sale, purchase or trade of blood and blood components intended for transfusion.

Wholesale Distributor Any person engaged in wholesale distribution of prescription drugs, including but not limited to:

- a. manufacturers;
- b. repackers' own-label distributors;
- c. private label distributors;
- d. jobbers;
- e. brokers;
- f. warehouses,
- g. including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;
- h. independent wholesale drug traders; and
- i. retail pharmacies that conduct wholesale distributions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:381 (April 1992), amended LR 29:1479 (August 2003).

Chapter 3. Wholesale Distributors

§301. Licensing Requirements

A. Every wholesale distributor who engages in the wholesale distribution of prescription drugs, to include without limitation, manufacturing in this state, shipping into this state or selling or offering to sell in this state, shall register annually with the Louisiana Board of Wholesale Drug Distributors by application for a license on a form furnished by the board and accompanied by a fee of \$200. The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

B.1. The license may be renewed annually at a renewal permit fee of \$200.

2. All licenses issued under this Section shall expire on December 31 of each calendar year.

3. Each application for the renewal of the license must be made on or before December 31 of each year, a penalty of \$50 per month from February 1 of the following year will be charged, provided that if the renewal is unpaid by April 1 of the following year, the license shall be null and void.

4. All licenses being reinstated must pay a reinstatement fee of \$200 plus the renewal fee of \$200.

C. Each license issued hereunder shall be displayed by the holder thereof in a conspicuous place.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 29:1480 (August 2003).

§303. Required Information

A. The Louisiana Board of Wholesale Drug Distributors requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

1. the name, full business address, and telephone number of the licensee;
2. all trade or business names used by the licensee;
3. addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;
4. the type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
5. the name(s) of the owner and/or operator of the licensee, including:
 - a. if a person, the name of the person;
 - b. if a partnership, the name of each partner, and the name of the partnership;
 - c. if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;
 - d. if a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

B. Where operations are conducted at more than one location by a single wholesale distributor, each such location shall be licensed by the Louisiana Board of Wholesale Drug Distributors.

C. Changes in any information required in this regulation shall be submitted to the Louisiana Board of Wholesale Drug Distributors within 60 days after such change.

D. Licenses are not transferable for change of location of the facility licensed or change of ownership. A new license application and required license fee must be submitted for location changes or change of ownership of a currently licensed facility.

E. Wholesale drug distributors with a place of business physically located in Louisiana must notify the board within three business days of the incident of any theft or diversion of legend or prescription drug product.

F. Wholesale drug distributors with a place of business physically located in Louisiana must notify the board within 24 hours of discovery of any counterfeit or misbranded legend or prescription drug product in their possession.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 29:1480 (August 2003), LR 30:1481 (July 2004).

§305. Qualifications

A. The Louisiana Board of Wholesale Drug Distributors will consider the following factors in determining eligibility for licensure of persons who engage in the wholesale distribution of prescription drugs:

1. any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. any felony convictions of the applicant under federal, state, or local laws;
3. the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
4. the furnishing by the applicant of false or fraudulent information in any application made in connection with drug manufacturing or distribution;
5. suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
6. compliance with the licensing requirements under previously granted licenses, if any;
7. compliance with the requirements to maintain and/or make available to the state licensing authorities or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors;
8. any other factors or qualifications the Louisiana Board of Wholesale Drug Distributors considers relevant to and consistent with the public health and safety.

B. The Louisiana Board of Wholesale Drug Distributors reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the interest of public health, safety or welfare.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992).

§307. Personnel

A. Personnel employed in wholesale drug distribution shall have appropriate education and/or experience to assume responsibility for positions related to compliance with state licensing requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992).

§309. Storage and Handling Requirements

A. The following are required for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees.

1. Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed or displayed shall:

- a. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- b. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
- c. have a designated and clearly identified quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
- d. be maintained in a clean and orderly condition; and
- e. be free from infestation by insects, rodents, birds, or vermin of any kind;
- f. drugs shall be redeemed from the quarantine area by the manufacturers identified by the NDC numbers thereof within 90 days after notification that such drugs are not saleable such prescription drugs shall be held in designated quarantine areas for not longer than 180 days.

2. Security

- a. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
 - i. Access from outside the premises shall be kept to a minimum and be well-controlled.
 - ii. The outside perimeter of the premises shall be well lighted.
 - iii. Entry into areas where prescription drugs are held shall be limited to authorized personnel.
- b. All facilities, with the exception of those facilities distributing medical gases only, shall be equipped with a monitored alarm system to detect entry after hours.
- c. Medical gas distributors shall store medical gases under lock and key if all medical gases are stored inside a board-approved storage facility that is not equipped with a monitored alarm system to detect entry after hours.
- d. Medical gas distributors that store medical gases on an open dock shall be equipped with a monitored alarm system to detect entry after hours.
- e. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion and provide protection against theft or diversion that is facilitated or hidden by tampering with computers and electronic records.

3. Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with requirements in the current edition of an official compendium.

a. If no storage requirements are established for a prescription drug, the drug may be held at room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

b. Appropriate manual, electromechanical, or electronic temperature recording equipment, devices, and logs shall be utilized to document proper storage of prescription drugs.

c. The recordkeeping requirements in §311 shall be followed for all stored drugs.

4. Examination of Materials

a. Upon receipt each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal exterior container damage that would suggest possible contamination or other damage to the contents.

b. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

c. The recordkeeping requirements in §311 shall be followed for all incoming and outgoing prescription drugs.

5. Returned, Damaged, and Outdated Prescription Drugs

a. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated in a clearly identified area from other prescription drugs until they are destroyed or returned to their supplier.

b. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated in a clearly identified area from other prescription drugs until they are either destroyed or returned to the supplier.

c. If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or

during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

d. The recordkeeping requirements in §311 shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 29:1480 (August 2003).

§311. Drug Distribution Recordkeeping

A. Wholesale drug distributors shall establish and maintain perpetual inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

1. the source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. the identity and quantity of the drugs received and distributed or disposed of; and

3. the dates of receipt and distribution or other disposition of the drugs.

B. Inventories and records shall be made available for inspection and photocopying by any official authorized by the Louisiana Board of Wholesale Drug Distributors for a period of three years following disposition of the drugs.

C. Records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by any official authorized by the Louisiana Board of Wholesale Drug Distributors.

D. Copies of licenses for customers who are authorized by law or regulation to procure or possess federal legend drugs shall be maintained for all customers that are shipped or sold federal legend drugs. If customer licenses are maintained off site, a list of customer names, addresses, license numbers, and license expiration dates shall be maintained for all customers that are shipped or sold federal legend drugs.

E. Medical gas distributors are not required to maintain a perpetual inventory on oxygen, but are required to maintain perpetual inventories on all other medical gases.

F. Wholesales domiciled in Louisiana must verify that their suppliers of legend drugs are licensed by the Louisiana Board of Wholesale Drug Distributors to ship or sell in or into Louisiana; and are responsible for notifying the board of any unlicensed wholesalers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:383 (April 1992), amended LR 29:1480 (August 2003).

§313. Policy and Procedures

A. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following.

1. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

a. any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Louisiana Board of Wholesale Drug Distributors;

b. any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

c. any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

3. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

4. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for three years after disposition of the outdated drugs.

5. A procedure to validate customer licenses, to review excessive or suspicious purchases, to inspect all incoming and outgoing shipments, and to monitor and record the temperature of product storage.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992), amended LR 29:1480 (August 2003).

§315. Responsible Persons

A. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage,

and handling, including a description of their duties and a summary of their qualifications.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992).

§317. Federal, State and Local Law Compliance

A. Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

1. Wholesale drug distributors shall permit the state licensing authority and authorized federal, state and local law enforcement officials upon having shown appropriate identification to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

2. Wholesale drug distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local, and DEA regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992).

§319. Salvaging and Reprocessing

A. Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Chapter 21, Parts 207, 210d, 211 of the Code of Federal Regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992).

§321. License Suspension or Revocation

A. The Louisiana Board of Wholesale Drug Distributors may revoke or suspend an existing license or may refuse to issue a license under this regulation if the holder or applicant has committed or is found guilty by the board of any of the following:

1. violation of any federal, state, or local law or regulation relating to drugs;

2. violation of any provisions of this regulation;

3. commission of any act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992).

§323. Penalties

A. After notice and hearing, whenever the board has found a licensee to have committed any prohibited act, the board shall have the power to impose a civil penalty and may order the license be suspended until the penalty is paid.

B. Before imposing any civil penalty, the board shall determine that the public health and welfare would not be impaired by the imposition of the penalty and payment of the penalty will achieve the desired disciplinary purposes.

C. No penalty imposed by the board shall exceed the \$1,000 per violation. The maximum aggregate penalty shall not exceed 50 times the maximum penalty per individual violation.

D. Each instance where a federal, state, or local law or regulation is violated shall constitute a separate violation.

E. The power and authority of the board to impose penalties is not to be affected by any other civil or criminal proceeding concerning the same violation, nor shall the imposition of a penalty preclude the board from imposing other sanctions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992).

§325. Premises and Records Inspections

A. The board may conduct inspections upon all premises, including delivery vehicles, purporting or appearing to be used by a person licensed under this regulation. The board, in its discretion, may accept a satisfactory inspection by The United States Food and Drug Administration (USFDA) or a State agency which the board determines to be comparable to that made by USFDA or the Louisiana Board of Wholesale Drug Distributors.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992).

Chapter 5. Powers and Functions of the Board

§501. Injunctive Powers

A. The board may, in its discretion, and in addition to various remedies provided by law under this regulation, apply to a court having competent jurisdiction over the parties and subject matter for injunctive relief to enjoin violations of this regulation or of any conduct which constitutes a clear and present danger to the public health and safety.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992).

§503. Board Domicile; Meetings

A. The board shall be domiciled in Baton Rouge, Louisiana. The regular meetings of the board shall be held at least two times a year in accordance with applicable law and at any other time the board deems necessary, at a time and place designated by the chairman. Special meetings may be called by the chairman upon giving at least 72 hours notice, sent by registered or certified mail to the post office address of each member of the board and to any persons who have previously indicated that they have business before the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 29:1481 (August 2003).

§505. Rules of Order

A. All meetings of the board shall be conducted in accordance with Robert's Rules of Order (Latest official edition).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992).

§507. Rule Promulgation

A. The board shall adopt, amend or repeal any rule or regulation to govern its actions in strict accordance with the Louisiana Administrative Procedure Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992).

§509. Inspection Contracts

A. The board may contract with any person or agency it deems qualified to conduct any inspections required by state or federal law.

B. The board shall retain exclusive jurisdiction to adjudicate all complaints, allegations or misconduct, or noncompliance by any licensee and to impose appropriate sanctions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 30:1481 (July 2004).

Chapter 7. Disciplinary Procedures

§701. Complaint Initiation

A. Complaints may be initiated by any citizen, corporate entity, the state of Louisiana acting through any of its departments, or by the board on its own initiative.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992).

§703. Complaint Investigations

A. Upon receipt of complaints or inquiries, the board shall take the following action.

1. Anonymous letters of complaint shall not be recognized as a basis for formal action.

2. If the information in the complaint is insufficient, the board may request further information by either written correspondence or the board may cause an investigation to be made.

B. All complaints received shall be assigned a docket code number which shall be utilized in all official references.

C. At its next meeting, the board shall officially receive and act upon all complaints and inquiries received.

D. The identity of all parties to a complaint shall be revealed to the involved parties unless it is certified to the board in writing by a proper law enforcement agency that to do so would jeopardize an ongoing criminal investigation.

E. The board shall inform the complainant of the action taken and any final result.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992).

§705. Complaint Withdrawals

A. If the complainant wishes to withdraw the complaint, proceedings thereto are terminated except in cases where the board judges the issue to be of such importance as to warrant completing the investigation in its own right and in the interest of public health, safety and welfare.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992).

§707. Hearings

A. Notice of Hearings. The board shall inform the party against whom a complaint has been made when said complaint appears to be sufficient cause for either suspension or revocation of a license. This notice shall notify the party against whom the complaint is made at least 30 days prior to the hearing and such notice shall conform to the requirements of the Administrative Procedure Act.

B. Disposition of Complaint. The board shall conduct such investigations, order such hearings, and take such other action as it finds necessary to make an intelligent decision on the complaint submitted for review.

C. Appearance. The party against whom the complaint has been made and upon notice being served, must appear at the date, time and place fixed for the hearing.

D. Default in Appearing. In the event the party against whom the complaint has been made fails to appear at the hearing provided for and also that notice has been given as to the hearing date, time and place, the party so failing to appear or otherwise obtain approval of the board for its absence shall be deemed to be in default and the evidence as received by the board at that time may be entered into the record and may be taken as true and the order of the board entered accordingly.

E. The procedure for notice, hearing and appeals therefrom shall be that of the Louisiana Administrative Procedure Act.

F. Hearing Procedure. The hearings called according to these rules and regulations shall be conducted by the board in accordance with the Administrative Procedure Act.

1. The chairman of the board or the vice chairman in the absence of the chairman shall announce the title and docket number of the proceeding before the board and shall introduce into the record evidence of the notice of hearing. Attorneys and/or other representatives of the accused party shall be recognized along with the representatives of the board and other proper parties.

2. The board shall then present its evidence subject to cross examination by the accused and any other proper parties.

3. The accused shall then present its evidence subject to cross examination by the board and any other proper parties.

4. The board may make a disposition of the case by stipulation, agreed settlement, consent, order, or default.

G. Board's Decision. The decision of the board shall be rendered within 30 days after the matter is submitted, shall be in writing, and shall be dated and mailed to the accused and his attorney, if any, by certified mail.

H. Rehearings. A decision or order of the board shall be subject to rehearing, reopening, or reconsideration by the board within 10 days from the date of its entry. Rehearings, reopenings, or reconsiderations shall be conducted in strict accordance with the Administrative Procedure Act.

I. Recording of Hearing. The board shall make a full recording of all proceedings before it and shall at the request of any party have prepared and furnished to him a copy of the transcript or any part thereof upon payment of the actual cost thereof.

J. Judicial Review of Decision. A person who is aggrieved by a final decision or order of the board is entitled to Judicial Review in accordance with the Louisiana Administrative Procedure Act whether or not that party has applied to the board for rehearing. Proceedings for Judicial Review may be instituted in the district court of the parish in which the board is located within 30 days after mailing of the notice of the final decision by the board or if a rehearing is requested, within 30 days after the decision thereon.

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AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992).

§709. Emergency Action

A. If at any point the board finds that public health, safety, or welfare requires emergency action, and incorporates a finding to that effect in its order, the board is hereby given authority to obtain a restraining order from a

judge of the appropriate court to suspend the license pending investigation or proceedings for disciplinary action. The order may be issued without bond. If the board seeks and obtains such a restraining order, the investigation and disciplinary action shall be commenced and completed as rapidly as possible.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:386 (April 1992).

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